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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,293	04/29/2006	Zhiqiang Gao	4276-103	8043

23448 7590 09/11/2009
INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

KAUR, GURPREET

ART UNIT	PAPER NUMBER
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1795

MAIL DATE	DELIVERY MODE
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09/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,293	Applicant(s) GAO ET AL.	
	Examiner GURPREET KAUR	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☒ Claim(s) 1,5 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/20/2007 and 11/13/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of claims

Claims 1-26 are pending and are being examined.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 has steps listed from (a) through (g), it should rather be (a) through (f). Appropriate correction is required.

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 5 in line 1 states "electrochemical activator is" it should rather state "electrochemical activator comprises."

Claim 15 is objected to because of the following informalities: There are two claims numbered 15. The claims need to be renumbered.

For the examination purposes, first claim 15 "The method of claim 10, wherein the analyte to be detected is a protein or a peptide" is numbered claim 15, however second claim 15 "The method of claim 15, wherein the capture molecule is at least on ligand capable of binding proteins or peptides" is numbered claim 16 and subsequent claims (claims 16-25) are being renumbered to claims (17-26) and their dependency is being changed accordingly to new claim renumbering.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 5, applicant claims electrochemical activator is n-phosphonic acid, where n= 0-12. However in the specification, the electrochemical activator is polymer chain with a phosphonic acid group as a terminal unit (see paragraphs 0026 and 0051).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "the agent" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "capture molecule" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-19 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Willner et al. (U.S. Pat. No. 6,214,205).

Regarding claim 1, Willner et al. teaches the method of electrochemical determination of the presence of the analyte in the liquid medium with a detecting electrode (electrode) (see abstract and col. 4, lines 16-20), the method comprising:

(a) immobilizing capture molecule (one recognition pair, antigen-antibody) which binds with analyte on the electrode (see col. 4, lines 19-21 and col. 3, lines 38-44);

(b) contacting electrode with liquid medium containing analyte (see col. 4, lines 25-30);

(c) allowing the analyte in the liquid medium to bind with the capture molecule (immobilized member) to form pair of complexes, the complexes are between the immobilized member and the analyte on the surface of the electrode to form a first layer (monolayer) on the surface of the electrode (see col. 4, lines 26-30, 64-67 over to col. 5 and col. 12, lines 32-34);

(d) contacting the electrode with electrochemical activator (first redox molecule), the first redox molecule is capable of transferring electrons to allow the detection of

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analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to form a second layer (electrochemical activator layer) on the electrode. Furthermore, both the second layer and first layer are conducting since the electron transfer occurs between the layers to detect the analyte (see figure 13A);

(e) contacting the electrode with an agent (second redox molecule) to transfer electron to or from the electrochemical activator from or to the electrode to give to an electrical response to indicate the presence of the analyte in the medium (see col. 4, lines 35-40), and ;

(f) detecting the analyte by comparing the result of electrical current (electrolytic oxidation of glucose) with that of control current (no electrolytic oxidation of glucose (see figures 3A-3B).

Regarding claims 6, 7, and 8, the agent (second redox molecule) is an enzyme (glucose oxidase) capable of transferring electron to and from the electrochemical activator (see col. 15, lines 39-47).

Regarding claims 9-11, capture molecules (recognition pair, oligonucleotide-oligonucleotide) which bind with analyte (oligonucleotide) on the electrode (see col. 4, lines 19-21 and col. 3, lines 38-44). It is well known in the art an oligonucleotide is a short nucleic acid polymer.

Regarding claims 12-16, the recognition pair, oligonucleotide-oligonucleotide has a complementary sequence (see col. 3, lines 41-45), it is inherent a complementary sequence of oligonucleotide recognition pair contains single strand nucleic acid with a pre-defined sequence. Willner et al. further teaches a recognition pair comprised of oligonucleotide-protein, wherein the analyte is the protein and capture molecule is oligonucleotide capable of binding to protein (see col. 3, lines 41-45).

Regarding claim 17, the electrode is soaked in the blocking agent (cystamine) as an preliminary step before the application of analyte (see col. 13, lines 22-38).

Regarding claim 18, Willner et al. teaches the method of electrochemical determination of the presence of the analyte in the liquid medium with a detecting electrode (electrode) (see abstract and col. 4, lines 16-20), the method comprising:

(a) immobilizing capture molecule (one recognition pair, antigen-antibody) which binds with analyte on the electrode (see col. 4, lines 19-21 and col. 3, lines 38-44);

(b) contacting electrode with liquid medium containing analyte (see col. 4, lines 25-30);

(c) allowing the analyte in the liquid medium to bind with the capture molecule (immobilized member) to form pair of complexes, the complexes are between the immobilized member and the analyte on the surface of the electrode to form a first layer

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(monolayer) on the surface of the electrode (see col. 4, lines 26-30, 64-67 over to col. 5 and col. 12, lines 32-34);

(d) contacting the electrode with electrochemical activator (first redox molecule), the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to form a second layer (electrochemical activator layer) on the electrode. Furthermore, both the second layer and first layer are conducting since the electron transfer occurs between the layers to detect the analyte (see figure 13A) and Willner et al. further indicate that a recognition pair is an enzyme-substrate (see col. 3, lines 40-45 and figure 3A) therefore inherently a capture molecule (enzyme) is capable of transferring electrons to or from the electrochemical activator or to the electrode and ;

(e) measuring electric current and detecting the analyte by comparing the result of electrical current with that of control current (see figures 3A-3B).

Regarding claim 19, Willner et al. teaches an electrode arrangement (system) comprising a detection electrode (electrode) for the detection of the analyte (see col. 8, lines 53-54 and col. 4, lines 16-20),

(a) electrode covered with monolayer comprising complexes (binding couple) between a capture molecule (recognition pair, antigen-antibody) which binds with analyte (see col. 8, lines 53-58 and col. 4, lines 26-30 and col. 3, lines 38-44);

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(b) the electrode is immobilized with electrochemical activator as second layer (first redox molecule layer) and the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to allow transfer of electrodes. Furthermore, both the second layer and the first layer are conducting since the electron transfer occurs between the layers to detect the analyte (see figure 13A)

Regarding claims 23 and 24, the agent (second redox molecule) is an enzyme (glucose oxidase) capable of transferring electron to and from the electrochemical activator (see col. 15, lines 39-47). The agent (second redox molecule) is bound with first redox molecule to form a bilayer (see col. 10, lines 21-27 and figures 4A and 4B).

Regarding claim 25, the electrode arrangement (system) is a biosensor since it detects analyte in the biological fluid (see col. 4, lines 44-45).

Regarding claim 26, Willner et al. teaches an electrode arrangement (system) for the detection of the analyte in biological fluid (see col. 8, lines 53-54 and col. 4, lines 16-20 and 44-45),

(a) a detection electrode (20) (see figure 3A);

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(b) electrode covered with monolayer comprising complexes (binding couple) between a capture molecule (recognition pair, antigen-antibody) which binds with analyte (see col. 8, lines 53-58 and col. 4, lines 26-30 and col. 3, lines 38-44);

(c) the electrode is immobilized with electrochemical activator as second layer (first redox molecule layer) and the first redox molecule is capable of transferring electrons to allow the detection of analyte upon complex formation (see col. 4, lines 1-24 and figures 3A-3B), thus it is inherent the electrochemical activator has net charge complementary to the electrostatic net charge of the complex formed to allow transfer of electrodes. Furthermore, both the second layer and the first layer are conducting since the electron transfer occurs between the layers to detect the analyte (see figure 13A);

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al. (U.S. Pat. No. 6,214,205) as applied to claims 1, 6-18 and 22-25 above, and further in view of Zhiqiang et al. (Electrodeposition of Redox Polymer and Co-Electrodeposition of Enzymes by Coordinative Crosslinking, *Angew.Chem.Int. Ed.* 2002, 41, 810-813).

Regarding claim 20, examiner is construing the agent is an electrochemical activator.

Regarding claims 2-4 and 19-21, Willner et al. teaches electrochemical activator is ferrocene monocarboxylic acid which inherently comprises iron metal ions (see col. 16, lines 6-8) but Willner et al. does not teach electrochemical activator is a polymeric redox polymer that comprises metal ions.

However, Zhiqiang et al. teaches a polymeric redox polymer deposit on the electrodes which further conducts electron transfer to oxidized/reduced substrates of the enzyme (see page 810, col. 1 paragraph 1 and col. 2, paragraph 1). The redox polymers are water soluble and readily bound to proteins and enzymes (see page 812 paragraph 1).

Zhiqiang et al. further teaches that polymeric redox polymer comprises osmium metal ions coordinated with the ligands (see scheme 1 on page 811).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to substitute polymeric redox polymer activator of Zhiqiang et al. with the Willner et al. electrochemical activator because polymeric redox polymer is water soluble and readily bound to proteins and enzymes to co-electrodeposit enzymes.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al. (U.S. Pat. No. 6,214,205) as applied to claims 1, 6-18 and 22-25 above and further in view of Wefers et al. (U.S. Pat. No. 5,132,181).

Regarding claim 5, Willner et al. does not teach electrochemical activator comprises n-phosphonic acid.

However, Wefers et al. teaches a functional layer disposed on the electrode surface comprised of polymer of phosphonic acid coordinated with a metal such as iron (see col.2, lines 26-35, col. 3, lines 15 and 37-41 and figure 1) to achieve higher performance in all types of bonding (see col. 7, lines 50-53).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to substitute electrochemical activator comprised of phosphonic acid of Wefers et al. with the Willner et al. electrochemical activator because the use of Wefers et al. activator achieve higher performance in bonding.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday (Alternate Friday Off), 8:00-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571)272-1263. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

/G. K./
Examiner, Art Unit 1795
9/2/09